Health, Aging and Body Composition (Health ABC) Trial

DXA Quality Assurance Manual for Hologic QDR-4500 Bone Densitometers

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1.0 INTRODUCTION

The purpose of this manual is to describe the DXA bone mineral density (BMD) quality assurance program for the clinical centers participating in the Health, Aging and Body Composition study. It provides information specific to the Hologic QDR 1500 and QDR 4500 and is intended as a supplement to the Hologic Users' Manual.

To use this manual effectively, it is essential that to have read and understood the entire Hologic QDR 4500 User's Manual. The study densitometry operators are required to have participated in a Hologic QDR 4500 training session and should be familiar with all instrument features and procedures discussed in the Hologic Users' Manual.

During the study, any questions regarding procedures that arise should be directed to:

Health ABC DXA Reading Center
University of California, San Francisco
74 New Montgomery St., Suite 600
San Francisco CA 94105

Telephone: (415) 597-9287
Fax: (415) 597-9213

IMPORTANT: Unauthorized changes in scanner software or personnel can have a large impact on the integrity of study data. If, for any reason, changes in any of these areas is anticipated, please contact the DXA Quality Assurance Center in San Francisco <u>in advance</u> for further instructions.

2.0 STUDY LOGISTICS

During the first year of the study, DXA scans will be acquired using both the QDR 1500 and the QDR 4500 as described below. At the end of the first year, follow - up scans will only be acquired on one machine (to be decided at a later date).

2.1 Screening, Eligibility and Enrollment

DXA scans will be obtained on the QDR 4500 scanner and the QDR 1500 provided for use in the Health ABC study No other scanner should be used.

Scans will be acquired according to the following schedule:

Baseline Visit :

QDR 1500	QDR 4500
Whole body (single beam)	Hip
	Whole Body

Follow-up Annual Visits:

Hip and Whole Body DXA scans will be obtained at each annual follow-up visit for all participants.

2.2 Division of Quality Assurance Responsibilities

2.2.1 Clinical center responsibilities

The clinical centers must ensure the overall quality and completeness of the DXA data and that all protocols and procedures are strictly followed. Specific responsibilities include the following:

1. require that technicians are properly trained and certified;

2. identify a chief densitometry operator to train and supervise other operators;

3. perform and review daily QC scans and scheduled cross-calibration scans of traveling phantoms;

4. assure that proper archiving and back-up procedures for patient scans are performed and that archives are stored securely on optical disks until the end of the study;

5. at specified intervals, send the following materials to the Health ABC DXA Reading Center :

   a. printouts of plots of the daily QC data
   b. updated copies of patient scan and machine repair logs
   c. original printouts of flagged scans
   d. original printouts of other requested scans
   e. traveling optical disk with all newly acquired scan files obtained since the last data transfer
   f. a copy of the current study database [DBARCHIVE] on a floppy disk

6. reanalyze centrally reviewed scans, as requested by the Reading center;

7. assure proper functioning of hardware and service from Hologic
   a. notify Hologic and the Health ABC DXA Reading Center of any machine or software problems, or if the QDR machine is being relocated
   b. record machine/software problems and service on the "service log"
   c. perform 5 QC phantom scans before, (if possible) and after service
   d. perform 5 QC phantom scans before and after a machine relocation

8. contact the densitometry specialists at the Reading Center with any questions or problems which cannot be dealt with in the biweekly batch mailings.

2.2.2 Health ABC DXA Reading Center responsibilities

The following are the responsibilities of the Health ABC DXA Reading Center:

1. write and maintain the quality assurance manual;

2. promptly review the daily QC phantom scan data received from each clinical center in order to identify surges or drifts in machine performance;

3. incorporate new participant data into the study wide database;

4. review certification and flagged scans and return results to each clinical center;

5. request and review random samples of scans from each clinic;

6. arrange for cross-calibration of all DXA instruments using traveling phantoms;

7. prepare quality control summary reports for Health ABC Steering Committee review;

8. identify possible sources of error, and suggest possible solutions. (**However, the Health ABC DXA Reading Center will not be responsible for the solution of a hardware or software problem; that will rest with the clinical center and Hologic.**)

9. review and evaluate special purpose phantom scans;

Any questions or correspondence regarding the manual or the technical aspects of the DXA measurements should be directed to:

Health ABC DXA Reading Center
UCSF Prevention Sciences Group
74 New Montgomery, Suite 600
San Francisco, CA 94105

Phone: (415) 597-9287 FAX: (415) 597-9213

2.2.3. Hologic responsibilities

The following are the responsibilities of the Hologic Inc.:

1. provide central training sessions for all Health ABC operators, if previously untrained (training to be paid for by the clinical centers);

2. provide hardware/software service within 24 hours, and work with clinic to resolve hardware or software problems;

3. work with the UCSF Quality Assurance Center in identifying and resolving any quality control or measurement problems.

2.3 Training and Certification of Health ABC DXA Operators

To obtain consistent results, the densitometry operators must be aware of possible sources of error that may affect data collection and analysis. Only those operators who have been certified through Hologic training and the Health ABC DXA Reading Center review are allowed to perform the scanning and analysis for this study.

Anyone performing scans for the Health ABC study must meet the following requirements:

1. read and understand both the Hologic QDR4500 manual and this manual;

2. successfully complete a Hologic QDR4500 training course;

3. satisfactory review of each operator's initial scans by coordinating center.

   In order for an individual technician to be certified to perform scans of a given skeletal site, the first 10 scans done on study participants at each skeletal site for each operator must be sent to the coordinating center for review. Original printouts of scans should be sent to the coordinating center at the address listed above as soon as the first 10 scans have been completed.

4. successfully pass the Reading center scan analysis tests;

It is the clinical center's responsibility to ensure that as new operators are brought into the study, all of the above certification criteria are met. Since the Hologic central training sessions are held infrequently, there may be several months delay between when a new operator is hired and when certification is complete.

Certification procedures for follow-up measurements

To ensure a high level of quality for the analysis of the follow-up scans, there will be an additional certification procedure for all BMD operators involved in the study. Each QDR operator will be required to send in baseline and follow-up scans of the first ten "1st annual" participants on which they perform densitometry in order to assess the analysis performance of each QDR operator.

Personnel not meeting these requirements may not scan patients without close supervision by a certified operator, unless specifically authorized by the Health ABC DXA Reading Center.

2.4 Health ABC DXA Reading Center Review of DXA Scans

Scan analysis quality will be ensured by a central review of analyzed participant scans. Whenever scans are to be reviewed centrally:

1. An original printout of the scan should be sent to the Reading Center.

2. It is the responsibility of the Health ABC clinic operator to reanalyze the scan according to the Reading Center comments and return a printout of the reanalyzed scan with an electronic copy to the Reading Center for verification.

Procedures for compiling and forwarding scans to the Health ABC DXA Reading Center are outlined in Section 5.

2.4.1 Certification Scans

The first 10 scans of each type (Hip, Whole Body) done on study participants by each operator must be sent to the Health ABC DXA Reading Center for review.

2.4.2 Training Scans

At the beginning of the study, and periodically during the study, a set of unanalyzed scans will be sent out to all sites. These scans should be analyzed independently by all DXA operators and the results of these analyses sent to the Health ABC DXA Reading Center. Successful analysis of these scans is required for certification and will also provide ongoing training of operators during the course of the study.

2.4.3 Flagged Scans

Any scans that appear unusual or difficult to analyze should be flagged for review by the Health ABC DXA Reading Center. Guidelines for flagging scans are listed in Section 3.4.

Flagged scans should be sent to the coordinating center monthly with the updated patient database. Note the reason(s) for flagging on the Health ABC DXA Scan Log and on the original printout, for clarification of the problem.

The printouts will be reviewed for standard positioning and analysis procedures and returned to the centers with instructions for reanalysis, if appropriate. Often, these problem scans have been analyzed correctly and will not require further action.

2.4.4 Random Samples of Scans

Periodically during the study, a random sample of scans will be requested for review by the Health ABC DXA Reading Center. In the initial phases of the study, a relatively large number of scans will be checked to verify site performance. The number of scans requested will vary according to the period in the study, the number and training of the technicians and the results of previous samples.

3.0 DXA Scan Acquisition and Analysis

Standard scanning and analysis procedures for the hip, and whole body bone density measurements are described in detail in the Hologic QDR 4500 Users' manual. Some of the information from the Hologic manual is repeated in this document for emphasis. Please note, however, that some of the scanning evaluation protocols for this study differ from those detailed by Hologic.

3.1 Participant data

This section describes in detail the specific procedures to be conducted for the Health ABC study with respect to entering the patient biography, scanning the patient and analyzing the scans.

Prior to scanning each participant, a Health ABC Bone Density form should be completed for that participant.

Each participant visit will be assigned a visit code. This code should be entered on the Bone Density form and in the Comment field in the Patient Biography. Use 0 (zero) for baseline, 1 for the first annual visit, 2 for the second annual visit and so on.

3.1.1 Patient Biography

Operator scan code, DOB, Sex, Weight, Height and Ethnic fields should be entered as described in the Hologic manual.

Patient Name Field: Enter the participant's last name then first name. Use Capital letters. An example of the PATIENT BIOGRAPHY screen for a patient with last name '**SMITH**' is shown in Figure 1.

```
_____________ Patient Biography Information _____________

  Name: SMITH, MARY
  Soc Sec:       Pat ID:  HA1000
  Comment: (Enter visit number, 0,1,etc)
  Scan Code:  ***           Zip:
  DOB: 10/20/30  Sex: F  Weight: 120  Height: 5' 0"
  Ethnic: W   Ref MD:HABC

_____________________________________________________________
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Figure 1. Patient Biography Screen

Patient ID Field: The enrollment ID consists of a 6 character combination of the clinic letter code and the patient number. **It is the single most important piece of information associated with each patient and must be entered precisely.** Consider the sample patient discussed above. Suppose the clinic ID is HA and the patient number is 1000, then Figure 1 demonstrates the correct method for entering the study ID within the Patient ID field.

Comment Field: Please enter the number (0, 1, 2, 3 etc.) corresponding to the particular visit in the "Comment" field.

Ref MD Field: Enter HABC

Be sure to use zeroes (0) and not the letter "O" when entering data into the Patient Biography fields.

3.2 Hip Scans

3.2.1. Hip Scanning

1 Refer to the “Side to measure” form to determine which hip to scan.

2 No metal or plastic object should remain in the scanning area. Check for jewelry, coins or other objects in the hip pockets, zippers, buttons, rivets, belts or any other clothing fasteners, as well as hip and back braces.

3 Keep the participant’s hands out of the scanning area by placing them well away from the hips.

4 Ensure rotation of the hip by holding the knee and the ankle when positioning the leg. Optimum positioning of the leg is most important to achieve a consistent projection of the femur. Scan the other side if you cannot rotate the foot inward due to pain.

5 After proper rotation, attach the leg to be scanned to the angled foot block supplied by the manufacturer.

6 The participant should be made as comfortable as possible to reduce the chance of unwanted movements. Use a pillow for the head and a small pillow under the knee of the leg not being scanned. Maintain the participant at a comfortable body temperature for the duration of the scan.

7 Instruct the participant to remain still until the end of the measurement. Make sure that the leg is not moved during the scan. Flag any scans in which the participant has moved and has not been rescanned.

Follow-Up

Before scanning the participant, load the baseline scan onto the hard disk and have a printout of the baseline available. Refer to the baseline printout as you go through the positioning of the participant for the follow-up; this is to ensure consistent scanning of the same area. Careful positioning and visual comparison of the current scan with baseline are essential for producing precise measurements. Consistent projection of the femur is more important than the actual angle of the foot rotation. Use the rescan feature as soon as any positioning errors are detected during the current scan.

3.2.2 Hip Analysis

Global Region of Interest The procedures outlined in the Hologic Manual are to be followed. The points listed below are for emphasis.

1. The lateral side of the global ROI should be at least 5mm (5 lines) beyond the outer edge of the greater trochanter to provide sufficient soft tissue for analysis, although it should not extend outside the participant's body.

2. The bottom edge of the global ROI should be at least 1cm (10 lines) below the lesser trochanter to provide sufficient soft tissue for analysis.

3. In order to facilitate the use of hip axis length software, the top and medial edges of the ROI should be expanded past the acetabulum to include the medial edge of the pelvic bone.

4. In the event that the global ROI must be expanded to allow complete filling of the bone edges (see below) in low BMD participants, all edges must be at least two steps away from the border of the scan field. This will be important when the baseline scan is used with the COMPARE feature on the follow-up scan analysis.

Bone Edges If the bone edges are not properly determined by the analysis program, increase the size of the global ROI by first moving the top border up 10 lines further from the femoral head, then by moving the medial border 10 lines further out, if possible, to include more soft tissue in the analysis. Repeat as needed. Do not move the bottom or lateral border. Do not fill in bone edges manually unless absolutely necessary. The software will automatically fill any "holes" within the bone. Occasionally, the bursa or tendons surrounding the greater trochanter can be calcified. This will produce "knobs" that can merge with the trochanter and throw off the automatic placement of the four regions. Expanding the global ROI will not always separate these from the trochanter and they will have to be manually excluded. Flag for review by the coordinating center any cases in which you manually alter the bone edge.

Femoral Midline Unevenness (notches) in the upper or lower edge of the femoral neck can throw off the femoral midline so that it does not run down the center of the neck. This will in turn cause the femoral neck box to twist. If the midline looks like it might be off or the box is twisted, it may be necessary to adjust the bone mask (e.g. filling in neck notches) in order to obtain appropriate positioning of the midline. The position of the midline itself should not be altered. If you have made changes to the scan such as filling in bone in order to alter the midline, or if the midline still seems off, please flag these cases for review by the coordinating center.

Femoral Neck Box If the default neck box provided by the Hologic program looks reasonably placed, leave it unchanged.

1. Whenever possible, use the maximum width of the neck box (default). The neck box should be perpendicular to the neck axis. Always anchor the neck box at the inflection, or "turning point" of the greater trochanter. On some scans, it will be necessary to lengthen the neck box in order to get correct placement of the neckbox. If the maximum area of the neck that can be covered by the femoral neck box is less than 1 cm^2, the participant should be rescanned with special care taken to improve the rotation and degree of adduction of the leg. Since such a narrow neck box would be only 2-3 lines wide, you will only rarely have a problem with this constraint.

2. If the area of the neck region is less than 2.5 cm^2, attempt to increase the width of the neck box to the maximum possible while still avoiding inclusion of the trochanter, ischium, or femoral head and acetabulum. In order to obtain maximum size of the neck box, the ischium may be deleted (see 4).

3. If the default neck box partially extends into the trochanter, or femoral head and acetabulum, adjust its location or size while maintaining the maximum possible area.

4. The Hologic software is sometimes unable to provide an appropriate placement of the neck box and other regions. This can occur if the projected neck axis is too short or the neck is too close to the ischium. Soft tissue between the neck and ischium will be read as bone, and the automatic placement of the femoral midline will fail. If this happens, use the procedure described in the Hologic manual for deleting the bone of the ischium. Deleting this will not adversely affect the analysis, as this bone is not included in the reported regions of interest.

Ward's Triangle The Hologic software should place the square marking Ward's triangle adjacent to the femoral neck box. In participants with low BMDs or short

femoral neck projections, the Ward's Triangle box may be misplaced considerably. If this happens, follow the instructions in the Hologic manual to modify the search region and flag the scan for review.

Trochanteric Line The trochanteric line should intercept the bone edge just below the lateral aspect of the greater trochanter. There is no need to correct minor deviations (up to about 3 pixels).

3.2.3 Reanalysis of Hip Scans

Always use 'Control-END' to confirm the general ROI of a hip scan for reanalysis of a baseline scan. All regions of interest will be recalculated. Ward's triangle and trochanteric line will be placed independently from the previous analysis. This procedure is absolutely necessary when you reanalyze your scans, to delete the ischium or filling in notches, for example. After accepting the general ROI proceed with the analysis of the hip scan as you did before.

3.2.4. Follow - up scans

Load the baseline scan onto the hard disk. Display this baseline evaluation using the COMPARE feature along with the current scan to be analyzed. It is important to realize that proper comparison of a follow-up hip scan to its baseline depends upon maintaining the identical size and relative position of the region markers. Vertical or horizontal shifts of these regions by one or more pixels can greatly alter the final values of the analysis.

Global Region of Interest

1. The width and height of the global ROI must be the same as that used on the baseline.

2. The dotted lines from the baseline defining the bone region should overlay the follow-up as closely as possible. Occasionally there are small changes in adduction and rotation of the leg which were not eliminated by rescanning. The region surrounding the neck should have the best fit.

3. If the global ROI cannot be moved to the appropriate position because it is too large, the baseline scan will have to be reanalyzed with a properly reduced global ROI. Then the follow-up should be analyzed comparing it to the reanalyzed version of the baseline. Flag cases in which the baseline had to be reanalyzed.

4. **Use <Control> <End>** to accept the global ROI and bone mask.

Bone Edges If the bone edges do not fill in properly on the follow-up analysis, first the baseline will have to be reanalyzed with a larger ROI, and then proceed with the comparison scan analysis.

Femoral Midline Unevenness (notches) in the upper or lower edge of the femoral neck can throw off the femoral midline so that it does not run down the center of the neck. This will in turn cause the femoral neck box to twist. If the midline looks like it might be off or the box is twisted on either the baseline or follow-up scan, it may be necessary to adjust the bone mask (e.g. filling in neck notches, deleting the ischium) in order to obtain appropriate positioning of the midline. The position of the midline itself should not be altered. If you have made changes to the scan such as filling in bone in order to alter the midline, or if the midline is still off, flag these cases for review by the coordinating center.

Femoral Neck Box If the current location is optimally matched to the location of the neck box of the baseline analysis, use it unchanged.

1. If the current location is not optimally matched to the location of the neck box on the baseline, adjust the current region to achieve maximum correspondence. The size of the neck box must be the same on both baseline and follow-up.

2. If the current location cannot be satisfactorily adjusted while maintaining the same sized neck box, reanalyze the baseline within the constraints outlined above.

3. It is most important to have the neck box location and size correspond as closely as possible. If you cannot get the neck boxes to match, flag the scan for review by the coordinating center.

Ward's Triangle If the Ward's triangle box appears on the follow-up scan in a significantly different position than on the baseline, or if after reanalysis of the baseline its location is different than that of the original baseline placement, flag the scan for review by the coordinating center.

Trochanteric Lines The trochanteric line should intercept the bone edge at the same point on all scans. Matching is easily done during the compare analysis, especially since you will have the baseline to consult during the compare.

3.3 Whole Body Scans

The HOLOGIC Operator's Manual should be consulted for the proper whole body scanning and analysis procedures. Clarifications and exceptions for the Health ABC Study are noted below.

3.3.1 Whole Body Scanning

3.3.2 Participant set - up

When performing whole body scans, attention has to be paid to the following points:

1. Have the participant remove all clothing, including shoes, and dress them in a hospital gown. Check that no metal or plastic objects remain in the scanning area. This includes hair clips and pins, underwire bras, snaps, zippers and buttons. Have patient remove any jewelry, earrings, bracelets, watches, or rings.

2. Position the participant in the center of the scanning table with their head just below the head of the table. It is extremely important that the participant is correctly positioned dead center on the table. The arms should be separated from the sides of the body with the hands placed palm down, within a few centimeters of the table edge.

3. Place a loop of tape around the top of the feet so that the feet are straight (or slightly inverted) - this will help to prevent motion during the scan and bring the femoral necks into better position for scan analysis.

4. Verify that the participant is aligned with the scanner axis (solid line on the table). If during scanning it is apparent that part of the patient's body lies outside the scan field, restart the scan.

5. The participant should be positioned as comfortably as possible since this reduces the chances of unwanted movements. In general, try to avoid to use any pillows or blankets. If the participant feels uncomfortable in that position, you may use pillows for the head only after the upper half of the scan is done. You may then carefully place a pillow under the head of the participant without causing motion artifacts. This procedure should be practiced with the participant before scanning. If the participant cannot lie flat at all without the aid of a pillow (due to kyphosis), use a radio- lucent pillow.

6. If the participant is very tall, try to include their feet in the scan by placing their head near the very top of the table.

7. Instruct the participant not to move until the end of the measurement.

Scan acquisition

QDR 1500	QDR 4500
Scan mode - single beam.	Scan mode - Array
Scan the tissue bar with the participant.	

3.3.3. Whole Body Scan Analysis

Baseline

1. Locate the horizontal shoulder line just below patient's chin.

2. The vertical shoulder lines should bisect the shoulder joints and separate the arms from the trunk. Avoid including any body soft tissue in the arm ROI.

3. Align the spine ROI with the curvature of the spine, if possible. Divide the spine at the T12-L1 disc space.

4. The horizontal line above the pelvis should be just above the iliac crest. The angled lines defining the pelvic triangle so that they bisect the femoral neck.

5. The vertical line between the legs should run between the patient's feet and evenly divide the legs. The lateral leg lines should be moved to include as much of the thigh soft tissue as possible without crossing the hands.

6. Cutline placement should be such that left/right symmetry is maintained i.e. placement of lines on the left side of the body should match those on the right.

Follow-up

For evaluations of follow-up measurements, display the baseline evaluation using the COMPARE feature and compare it to your current image on the screen.

Match the location of the region markers as closely as possible to the baseline measurement. Optimally matched in this context means that the markers should be at the same position between the body regions as on the baseline image.

If adjustment cannot be done satisfactorily, it will be necessary to reanalyze the baseline scan. If it is necessary to reanalyze the baseline measurement, all subsequent follow-up measurements should be reanalyzed using COMPARE.

3.4 Scan Flagging criteria

General

- Scan has unusual appearance or is difficult to analyze
- Any of the following in scan field (either in the bone or soft tissue)
  Unusual anatomical variations
  Surgical hardware
  Patient motion during scan
  Superimposed buttons, pins, zippers, pacemakers, vitamin pills, etc.
- ROI used on follow-up is different size than used at baseline
- Bone edges have been altered in any way
- Follow-up scans cannot be reasonably matched to baseline analysis

Hips

- Femoral midline misaligned and cannot be corrected by following the analysis procedures as outlined in the Health ABC manual
- Neck box width reduced from default
- Ward's triangle persistently located outside of Ward's region - difficulties in redefining search region
- Analysis program repeatedly fails to place regions appropriately - major operator interaction required for analysis
- Excessive bone loss

Whole Body

- Patient motion without rescanning (these scans are extremely susceptible to motion artifacts)
- Significant changes in positioning between baseline and follow - up scan.
- Unable to fit both arms in scan field
- Unable to locate tissue bar on QDR 1500 scans

4.0 Scanner Quality Control

Monitoring of machine performance throughout the study is the joint responsibility of the individual clinical centers and the Health ABC DXA Reading Center.

4.1 Daily Phantom Scans

Perform the daily QC phantom scans as outlined in the Hologic manual. The results of these scans should be reviewed locally for abrupt changes in machine performance and the results sent to the coordinating center once a month. Points of procedure to note:

QDR 1500

1. Create only one patient biography per phantom. Avoid duplication of phantom biographies by using the patient menu to select the appropriate biography prior to scanning the phantom.

2. Scan the phantom on top of the pad. Ensure alignment with the scanner axis by using the phantom case as a spacer to line up the phantom(one side of the case against the scanner's side panel and the opposite side serving as a guide to position the phantom).

3. Analyze the daily phantom scans using the COMPARE feature. **Keep the original scan that you use as the "baseline" for the compare permanently stored on the hard disk.** At least two backup copies of this baseline phantom scan should be stored on your optical disks or on two floppy disks.

4. Add the scan to the QC database immediately after scanning and analysis are complete.

QDR 4500

1. Create only one patient biography per phantom. Avoid duplication of phantom biographies by using the patient menu to select the appropriate biography prior to scanning the phantom.

2. Scan the phantom on top of the pad. Ensure alignment with the scanner axis by using the laser cross - hairs.

3. Add the scan data to the QC database immediately after scanning and analysis are complete.

Both machines

Use the plot feature daily to verify that the BMD, BMC and AREA values of your scanner are within normal limits - for the Whole Body phantom, check BMD and %Fat values and plot manually on graph paper. If the most recent scan falls outside the limits, reposition the phantom and repeat the scan. **If the second scan also falls outside the limits, contact both Hologic and the Health ABC DXA Reading Center.**

After the phantom scan has been analyzed and added to the QC database, delete that day's **scan** from the hard disk. **Note: the Whole Body phantom scans should be archived to an optical disk before being deleted from the hard drive.**

If the CV of the BMD exceeds 0.60% please contact both the Reading Center and Hologic to initiate appropriate action.

Check the system drift weekly by pressing <R> while viewing the plot. The slope of the calculated regression line should be within the range of the standard deviation shown. If the drift is greater than the standard deviation, contact both Hologic and the Reading center.

Generate a printout of the daily phantom plots (BMD, BMC and AREA for hip, spine and ESP phantoms; BMD and % Fat for the Whole Body phantom) once a week on your designated "QC day." This will facilitate detection of long-term drifts as well as short-term inconsistencies.

Original printouts including the scan results of the most recent daily phantom QC plots (BMD, BMC and AREA for hip, spine and ESP phantoms; BMD and %Fat for the Whole Body phantom) are to be sent to the Reading Center for review biweekly. The date range for the plots should cover the previous 6 months to the present. The plots for the Whole Body phantom will need to be charted manually.

Perform a dBarchive at least once a week.

In addition to the daily scanning of the Hologic spine phantom, a number of different phantoms will be used for Health ABC to monitor machine performance and for cross calibration purposes. The schedule for scanning these various phantoms can be found in the table below.

Phantom	Scanning frequency
Local Hologic Hip phantom	2 times / week (4500 only)
Local Hologic Whole Body phantom	3 times / week (4500) 2 times / week (1500)
European Spine phantom	3 times / week (4500) (every other month)
Hologic "Gold Standard" Hip, Spine and Block phantoms	Annually

The European Spine Phantom will be rotated between the two clinics on a monthly basis.

4.2 Cross-Calibration of Scanners

In order to accurately assess absolute variations in scanner performance between clinical centers, periodically throughout the study phantoms will be either mailed or brought to each of the field centers and scanned. The Hologic hip, spine and block phantoms, Whole Body phantom and the European Spine Phantom (ESP) will be used. A detailed protocol will accompany the phantoms.

4.3 Machine, Software and Service Problems

If your machine needs to be repaired or if any adjustment has to be made that possibly might affect your data:

1. Do a dBarchive before any work is done on your QDR.

2. Contact the Reading Center before the repairs or adjustments are made to find out whether additional measures are required.

3. Perform 5 scans of the Hologic daily QC spine phantom before (if possible) and after the repairs or adjustments are made.

4. After repairs or adjustments are completed, send the repair technician's notes and a copy of the completed study repair log to the Health ABC DXA Reading center. The repair log should contain complete information on all repairs done on your machine. Please keep a repair log with your machine.

4.4 Software Change Control

Unauthorized software changes must be avoided. If for any reason you think you have to change the software, or your Hologic service representative recommends a software change, contact the Health ABC DXA Reading center before any changes are made.

The system software installed on the Health ABC QDR 4500 densitometers should be Version 9.03. You can find your version number at the top of the blue Hologic menu. It will say "Hologic QDR 4500 version 9.03". The system software on the Health ABC QDR 1500 should be Version 7.20. Future software upgrades will be checked by the UCSF Quality Assurance Center in conjunction with Hologic technical support personnel to assure that the upgrade will not adversely affect the study. Authorized upgrades must be cleared by the Health ABC DXA Reading Center before installation at the study sites.

5.0 Data Management

5.1 Hard Copies of Scans

The study site is responsible for maintaining original hard copies of all scans performed during the study. Keep the original printouts in the participant's scan printout folder. The following printed reports are needed for each scan:

Proximal femur: print the standard report.

Whole body: print the BMD and body composition reports (2 pages).

5.2 Electronic Scan Archive

For scan archival, each study site works on a two optical disk system. (There will also be two "traveling opticals" for sending scan images for central review.) Both optical disks are continually updated at the end of each day using the Optical 1 and Optical 2 options under the Hologic archive menu. Please be sure to rearchive any scans that you reanalyze after you have completed the reanalysis. In order to use the

optical disks efficiently, do not save or archive scans individually. Saving scans in batches (e.g. at the end of a day) will ensure the longevity and efficient usage of the optical disk space. The QDR software will give a warning message when optical capacity has been reached. Fill side A of the disk first, then fill side B. (See the Hologic User's Manual for detailed instructions.). The ODC2 should be a dedicated Health ABC optical, used only for archiving scans acquired for Health ABC.

Scans to be archived **each day** to the Optical 1, Optical 2 and "traveling" optical disks include:

1. all new patient scans acquired since the last archive was performed;

2. all scans that have been reanalyzed since the last archive; (Note that if a scan needs to be restored and reanalyzed for any reason, it will need to be rearchived.)

Optical 1 and 2 will remain at the study site at all times. (The "traveling opticals" will be sent back and forth between the study site and the Health ABC DXA Reading Center.)

The clinical centers are responsible for following the archive schedule and for keeping the optical disk archives safe until the end of the study.

5.3 Transfer of Data to the Health ABC DXA Reading Center

The following items are to be sent to Reading center at the end of each month (except QC plots):

1. QC PRINTOUT. Send a printout of the most recent plots of the QC database, (spine, hip, ESP and Whole Body phantoms - BMD, BMC and AREA). The plots are reviewed at Reading Center, and problems are reported back to the clinic. (**Send biweekly**)

2. PARTICIPANT SCAN LOG. Send a copy of the written patient scan log sheet covering participants scanned since the last data transfer. Use the log sheets to "flag" individual scans for review at the Reading Center.

3. SCANS FOR REVIEW. Send original printouts of certification scans, "flagged" scans, random sample scans, and any scans requested for review by the Reading Center. Please write the reason the scan was flagged, requested or being sent directly on the printout. These scans will be triaged visually

based on the original printouts and analyzed on the Hologic workstation if necessary.

4. TRAVELING OPTICAL DISK . Send electronic copies of all scans acquired and reanalyzed since the last data transfer. Archive scans using the COPY feature. Do not archive the scans individually as this will use up the disk space rapidly.

5. REANALYZED SCANS. Send original printouts of all scans which have been reanalyzed according to the coordinating center instructions since the last data transfer. Attach the annotated printouts sent by the coordinating center which indicated the problems requiring reanalysis. You MUST also send back the reanalyzed scan images on the traveling optical.

6. DB ARCHIVE patient database (on floppy disk). Please include the following on the disk label:
"DB ARCHIVE"
batch #
clinic name
date (end date of 1 month period)
if more than 1 disk, label each disk as above and 1 of 3, 2 of 3, etc.

Diskette Label for DB Archive

Health ABC
DB Archive
Date _____
Clinic_____
Batch #_____
Diskette No. ____ of ____

Please note: The Reading center will use the <u>most recent scan data</u> for participants whenever there are multiple analyzed scans from the same date in the data base. Please notify us if there are exceptions to this.

7. Copy of the Maintenance/Repair Log (with a copy of the Hologic service report).

Pack the materials carefully. The optical disk should be placed in a plastic bag and then wrapped in plastic bubble wrap to avoid damage. Batches containing the optical disk should be send via FedEx/UPS.

Assign a number to each batch of BMD data, beginning with the first batch of BMD materials sent. Start with batch number 001. The batch number should be the clinic identifier followed by this 3 digit number. Thus the batch number should be a 5 digit field: e.g. for the Memphis clinic, batch number 1, the number should be HA001.

Complete a BMD Batch Checklist, indicating the number and which materials are included in the batch, and send it along with the batch materials.

The materials in the batch should be bundled separately by type.

Ship these items monthly to the following address:

Health ABC DXA Reading Center
UCSF Prevention Sciences
74 New Montgomery, Suite 600
San Francisco, CA 94105

5.4 Return Materials Sent by the Reading Center

The Health ABC DXA Reading Center will return the following items to the study site after review:

1. Annotated printouts of flagged scans, random sample scans, and any other requested scans are returned to the study site with explicit instructions for reanalysis, as necessary. The clinic then reanalyzes the problem scans according to the Reading Center recommendations. The reanalyzed scan is then saved and rearchived and the database at the study site is automatically updated. An original printout of the reanalyzed scan is sent to the Reading Center with the next data transfer to verify compliance.

2. Traveling optical.

3. Any recommendations for service, additional phantom scans, etc., as necessary based on the quality control database.

APPENDIX A. STUDY FORMS

The following forms are included in this Appendix:

Batch Record Form

Bone Density Form

Hologic Maintenance/Repair Log Sheet

DXA Scan Log

Master copies of the forms will be mailed directly to your site. Always keep a copy of any form you send to the HABC DXA Reading Center

HEALTH ABC
BMD BATCH RECORD FORM

Batch Number: _____ **Date Batch Mailed:** ____ /____ /____ (Month / Day / Year)

Clinic Name: _____

Contents: (check Yes or No)

DB Archive Disk	☐ Yes	☐ No	Date Archived: ____ /____ /____ (Month / Day / Year)
QC DB Printout	☐ Yes	☐ No	Date Printed: ____ /____ /____ (Month / Day / Year)
Scan Log Sheet	☐ Yes	☐ No	
Flagged Scans	☐ Yes	☐ No	Number: _____
Reanalyzed Scans	☐ Yes	☐ No	Number: _____
Random Sample Scans	☐ Yes	☐ No	Number: _____
Other Scans	☐ Yes	☐ No	Number: _____
(specify: _____)			
Traveling Optical	☐ Yes	☐ No	

Certification Scans:

Staff ID	Number of Scans	Scan Type
_____	_____	_____
_____	_____	_____
_____	_____	_____

Staff ID#: _____

Version 1.0, 3/28/97

Health ABC

BONE DENSITY (DXA) SCAN

Staff ID #

1 Visit type:

☐ Baseline clinic visit

☐ Non-routine clinic visit ***Reason:*** _____

2 Review Side to Measure Assessment Form to determine which hip to scan.

a. Has the participant had knee or hip replacement?

☐ Yes ☐ No

→ Indicate side & location on next page, section 5.

b. "Have you had any other joint replacement, such as shoulder, elbow?"

☐ Yes ☐ No

→ Indicate side & location on next page, section 5.

3 "Do you have any metal objects in your body, such as a pacemaker, staples, screws, plates, etc."

☐ Yes ☐ No

→ ◆Indicate side & location in the table on next page
◆Flag scan for review by DXA Reading Center

4 "Do you have breast implants?"

☐ Yes ☐ No

→ ◆Flag scan for review by DXA Reading Center

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Version 1.2, 8/13/97

Health ABC

BONE DENSITY SCAN -- Page 2

5 Indicate in the table below the location of joint replacement, hardware or other artifacts (sub regions are those defined by the whole body scan analysis.)

Sub	Hardware	Other Artifacts	Comments
Head	☐	☐	_____
Left arm	☐	☐	_____
Right arm	☐	☐	_____
Left ribs	☐	☐	_____
Right ribs	☐	☐	_____
Thoracic spine	☐	☐	_____
Lumbar spine	☐	☐	_____
Pelvis	☐	☐	_____
Left leg	☐	☐	_____
Right leg	☐	☐	_____

6 "Have you had any of the following tests within the past ten days?"

	Yes	No
a. Barium enema	☐ *	☐
b. Upper GI X-ray series	☐ *	☐
c. Lower GI X-ray series	☐ *	☐
d. Nuclear medicine scan	☐ *	☐
e. Other tests using contrast ("dye") or radioactive materials	☐ *	☐

* ***(If yes to any, reschedule bone density measurement so that at least 10 days will have passed since the tests were performed.)***

7 Was a bone density measurement obtained for...?

QDR4500

a. Whole Body ☐ Yes ☐ No

Last 2 digits of scan ID# ☐☐

b. Hip ☐ Yes ☐ No

☐ Right ☐ Left

Last 2 digits of scan ID# ☐☐

QDR 1500

c. Whole Body ☐ Yes ☐ No

Last 2 digits of scan ID# ☐☐

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Version 1.2, 8/13/97

HABC MAINTENANCE & REPAIR LOG SHEET

Clinic name: ..... Date: .....

1. Describe problem (incl. dates): .....
.....
.....
.....

2. Did problem affect scans or BMD data?

o Yes o No

If yes, describe: .....
.....
.....

Did problem cause downtime of scanner? o Yes o No
If yes, for how long?.....

3. Describe the action taken by you (including repair by Hologic)? .....
.....
.....
.....

4. Was the problem resolved?
o Yes o No
If not, please specify:.....
.....

5. Was a recalibration of the device necessary?
o Yes o No

6. Were phantom scans performed after the repair or the recalibration?
o Yes o No

If yes, did you notice a change in the phantom BMD values?
o Yes o No

Please fill in the form thoroughly. Send one copy together with the technician's repair invoice to the UCSF QA Center. Keep one copy with your scanner in your own repair log.

Sheet

HABC DXA Scan log QDR 4500

Clinic:

Date	Pat ID	Acrostic	Scan Type	Scan #	Flagging	Comments
			Whole Body			
			Hip			
			Whole Body			
			Hip			
			Whole Body			
			Hip			
			Whole Body			
			Hip			
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			Whole Body			
			Hip			

APPENDIX B. CROSS CALIBRATION PHANTOM PROTOCOLS

The following protocols are included in this Appendix:

Spine Phantom Protocol

Hip Phantom Protocol

Block Phantom Protocol

European Spine Phantom Protocol

Whole Body Phantom Protocol

DXA Scanner Cross - Calibration using the Hologic Quality Control Phantoms and the European Spine Phantom (ESP)

Scanning and Analysis Procedures for Hologic QDR Systems: QDR-4500

Table of Contents:

Scanning in Array Mode:

Perform the following scans:

Spine: 5 Array Spine scans.

Hip: 5 scans as an Array **Right Hip**.

Block: 5 Array Spine scans.

IMPORTANT NOTE:

WHEN PERFORMING THESE CROSS CALIBRATION SCANS COMPLETE TWO SCANS OF EACH PHANTOM (WITHOUT REPOSITIONING THE PHANTOM BETWEEN SCANS) ON ONE DAY THEN COMPLETE 3 SCANS OF EACH PHANTOM (AGAIN WITHOUT REPOSITIONING THE PHANTOM BETWEEN SCANS) ON A DIFFERENT DAY.

Hologic Spine Phantom Scanning

1. Create a Patient Biography (unless one already exists for this phantom) in the following manner.

   Name : **SPINE PHANTOM #1162** *(Note: there is a space between the word phantom and the # sign)*

   Pat ID : **HX#1162** 'H' denotes HABC, 'X' is your site # enter A or B as appropriate), and '1162' is the Hologic Spine X-cal. phantom serial # . *Please use zeros (Ø) in the biography and not the letter "O".*

   Sex : **F**

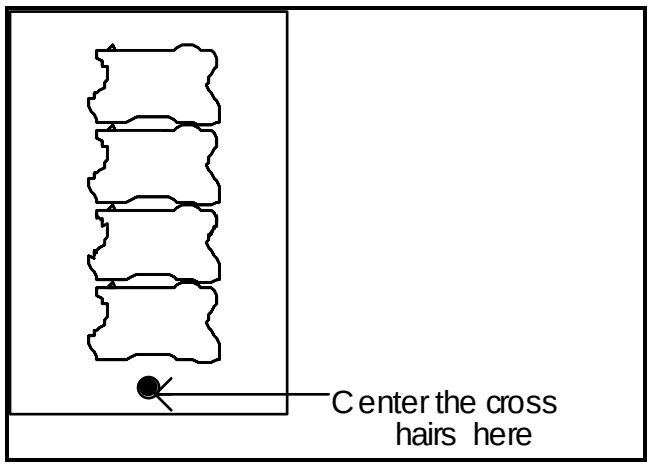
   Ref MD: **HABC** *all other fields in the Patient Biography should be left blank*

2. Place the Spine Phantom on the mat. Make sure it is straight on the table. Use the top of a phantom box to align the phantom and move the cross hairs from head to foot along the edge of the phantom to check the alignment.

3. Go to the scan menu <**F3**> and choose "**Spine**". Then select '**Array Spine**' as the scan type. After the arm moves to the back press <**Enter**>. The arm will move forward to the correct centering point for the scan.

4. Position the cross hairs over the black star on the spine phantom. Be sure the black star is located at the foot end of the scanning table.

Set scan length to 6 inches or approximately 15 cm.



5. Press <**F2**> to Scan. Use <**F3**> (rescan) if Phantom is not centered or does not have all vertebrae visualized. Do not stop the scan prematurely. **Do not include air in the scan field.**

Creating a Hologic Spine Phantom Baseline Analysis

1. Select Region of Interest (ROI)

   A) The width is automatically set to 116 pixels in array mode.
   Do not alter the width from the default size.

   B) Ensure that the intervertebral markers lie within the intervertebral spaces. They must not intersect any of the vertebral bodies.

   C) Center the ROI so the Spine Phantom is in the middle.
   Press **<End>**.

2. Mark Inter vertebral Spaces.
   Be sure the lines are placed equidistant in the disk space.
   Press **<End>**.

3. Label Vertebrae.

   A) Confirm L1 - L4 labels.
   Press **<End>**.

   B) At this point, the QDR begins its calculations of the soft tissue and bone thresholds. Wait until the calculations are completed before processing any further.

4. **DO NOT INSERT OR DELETE ANY POINTS**

Press **<End>**.

5. The Report Screen.
Print the report for this scan.

Hologic Spine Phantom Compare

1. Once a baseline Hologic Spine Phantom scan has been established, use that scan as the reference scan within the **Compare** feature menu for all subsequent scans.

2. After a subsequent scan has been performed, choose 'Compare' at the Analyze menu.

3. Highlight the Baseline Hologic Spine Phantom and press <**ENTER**>.

4. Analysis.

A) Two images are displayed on the screen. The one on the left is the present scan.

B) The ROI and bone outline are automatically placed over the scan. Using the arrow keys, move the entire box so it matches as best as possible over the image. When comparing Spine scans, move the ROI up and down or left and right as necessary.

Press **<End>**.

C) Mark Intervertebral Spaces. If the ROI was matched correctly, no adjustment should be necessary.
Press **<End>**.

D) Label Vertebrae. This is done automatically.
Press **<End>**.
At this point, calculations begin. Please do not interrupt them.

E) **DO NOT INSERT OR DELETE ANY POINTS.**

Press **<End>**.

F) The Report Screen is generated.
Print the reports for the remaining scans.

Hologic Hip Phantom Scanning

1. Create a Patient Biography (unless one already exists for this phantom) in the following manner.

   Name: **HIP PHANTOM #202** *(Note: there is a space between the word phantom and the # sign)*

   Pat ID : **HX#202** 'H' denotes the study , 'X' is your site # - enter A or B as appropriate, and '#202' is the Hologic Hip X-cal. phantom serial # . *Please use zeros (Ø) in the biography and not the letter "O".*

   Sex : **F**

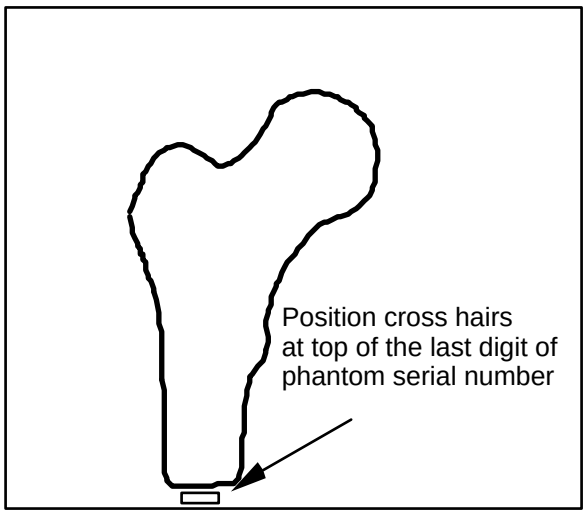
   Ref MD: **HABC** *all other fields in the Patient Biography should be left blank*

2. Place the Hip Phantom on the mat. Make sure it is straight on the table. Use the top of a phantom box to align the phantom and move the cross hairs from head to foot along the edge of the phantom to check the alignment.

   Scan as an Array **RIGHT Hip**.

3. For an Array scan of the hip phantom, use the same positioning procedure as for a patient. Position the cross hairs as shown in the diagram below.

4. Scanning:



A) Scan in Array mode.

B) Use default length (6 cm) and width.

C) Use **F3** (rescan) if you do not have all of the shaft of the femur included. There should be at least 4 scan lines below the end of the phantom's femoral shaft.

D) Let the scan complete itself. **Do not include air in the scan field.**

Creating a Hologic Hip Phantom Baseline

1. Select Region of Interest.

   A) Make the ROI box size 101 x 144.

   B) Place the lower line four steps (pixels) below the base of the femoral shaft.

   C) Center the ROI to the Hip. Press **<End>**.

2. Insert or Delete Points.
   Press <**End**>**.**

3. Mark Femoral Midline.
   Press **<End>**.

4. Position Box on Femoral Neck.

   A) Press <**Insert**> to move entire neck box as a unit. Do not alter the neck box size, it should be left with its default values.

   B) Press <**Ctrl>** and <**Page Down** > 3 times.
   This slows the movements of the box.

   C) Adjust the position of the neck box to align with the trochanter at the turning point. See the figure at the end of this section.
   Press **<End>**.

5. Position Box on Ward's Triangle.

   A) Press <**Insert**>.
   B) Press <**Ctrl** and **Page Down**> 3 times.
   C) Align Ward's with the femoral midline. See the figure on the next page.
   D) Adjust Ward's so that it is two steps (pixels) below the femoral neck box.
   Press <**End**>.

6. Mark Base of Trochanter. Press <**End**>.

7. Final report.
   Print the report for the scan

Hologic Hip Phantom Compare

1. Once a baseline Hologic Hip Phantom scan has been established, use that scan as the reference scan within the Compare feature menu for all subsequent scans.

2. After a subsequent scan has been performed, choose **Compare** at the Analyze menu.

3. Highlight the Baseline Spine Phantom and press <**ENTER**>.

4. Analysis.

A) Two images are displayed on the screen. The one on the left is the present scan.

B) The ROI and Mask are automatically placed over the scan. Using the arrow keys, move the entire box so it matches as best as possible over the image.

Press **<End>**.

C) Insert or Delete Points.

Press **<End>**.

D) Mark Femoral Midline.

Press **<End>**.

E) Anchor the Neck Box on the Femoral Neck. The following steps must be done in Compare for the Phantom ONLY.

a. Press <**Insert**> to move entire box.

b. Press <**Ctrl** and **Page Down**> 3 times. This slows the movements of the box.

c. Adjust the position of the neck box to align with the trochanter at the Inflection point (also called the turning point).

See the figure on the next page

Press **<End>**.

F) Position Box on Ward's Triangle.

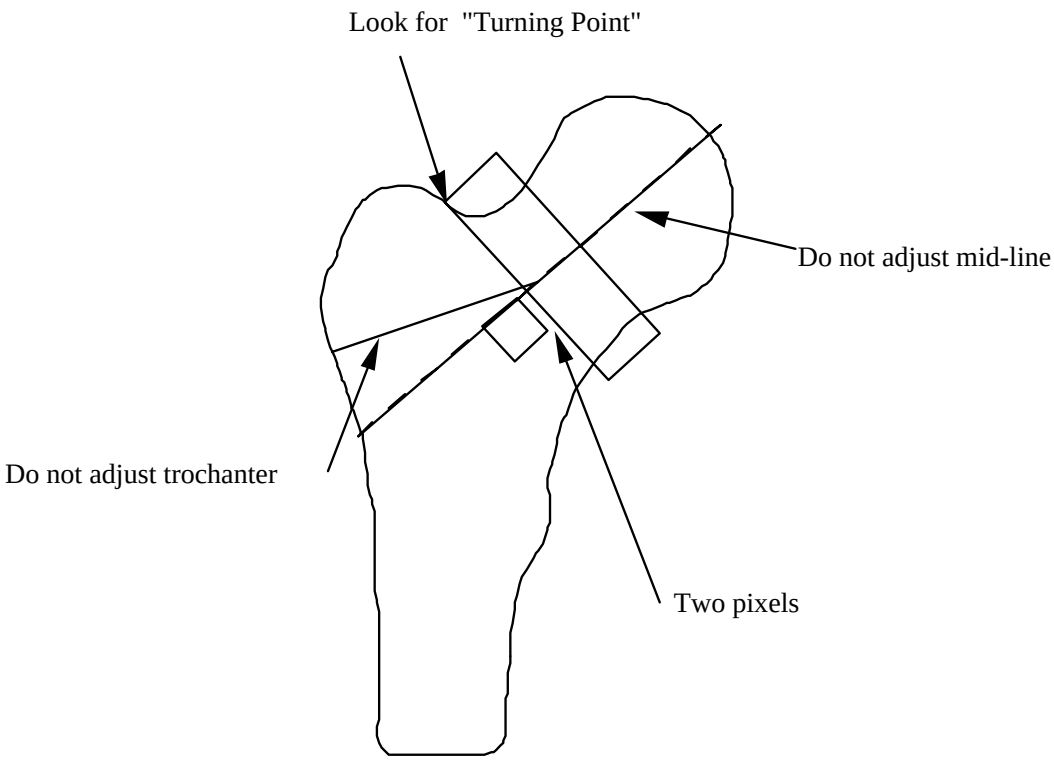
a. Press <**Insert**>.

b. Press <**Ctrl** and **Page Down**> 3 times.

c. Align Ward's with the femoral midline. See the figure below.

d. Adjust Ward's so that it is two steps (pixels) below the femoral neck box. See the figure below.

Press **<End>**.



Please note that the positioning of Ward's Triangle should only be done for the Cross calibration scans. Do not adjust Ward's Triangle in study patient scan analysis.

G) Mark Base of Trochanter.

Press **<End>**.

5. Final Report
Print the reports for the remaining scans.

Hologic Block Phantom Scanning

1. Create a Patient Biography (unless one already exists for this phantom) in the following manner.

Name : **BLOCK PHANTOM #303** *(Note: there is a space between the word phantom and the # sign)*

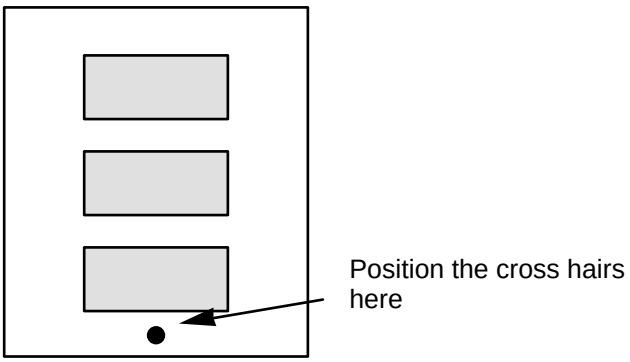
Pat ID : **HX#202** 'H' denotes the study , 'X' is your site # - enter A or B as appropriate, and '#303' is the Hologic Block X-cal. phantom serial # . *Please use zeros (Ø) in the biography and not the letter "O".*

Sex : **F.**

Ref MD: **HABC** *all other fields in the Patient Biography should be left blank*

3. Place the Block Phantom on the mat. Make sure it is straight on the table. Use the top of a phantom box to align the phantom and move the cross hairs from head to foot along the edge of the phantom to check the alignment.

4. Center the cross hairs as you would for a spine phantom.



5. Scan as an array Spine.

Set scan length to 6 inches or approximately 15 cm.

Use <**F3**> (rescan) if you are not centered or do not have all of the blocks included in the scan field.

Allow the scan to finish on its own; do not stop it prematurely.
Do not include any air in the scan field.

Creating a Hologic Block Phantom Baseline Analysis

NOTE: DO NOT ANALYZE THE BLOCK PHANTOM SCANS - SEND THE UNANALYZED SCANS ON FLOPPY DISK TO THE HABC DXA READING CENTER. HOWEVER, THE SCANS SHOULD STILL BE ARCHIVED TO YOUR OPTICAL DISK

Archive and Data Shipments

After all of the scans have been run and analyzed, archive the scans to your optical disk and copy the scans to floppy or optical disk for shipment to the HABC DXA Reading Center.

Send printouts of the hip and spine phantom scans along with electronic copies of all scans on floppy disk to:

Maurice Dockrell
HABC DXA Reading Center
74 New Montgomery St., Suite 600
San Francisco CA 94105

DXA Scanner Cross-Calibration using the European Spine Phantom (ESP)

European Spine Phantom (ESP) Scanning

1. Create a Patient Biography in the following manner.

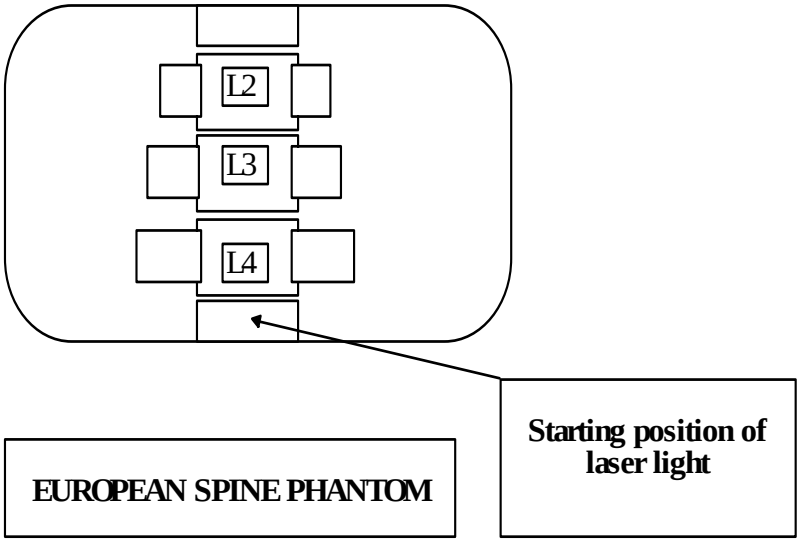
   Name : **ESP 123**

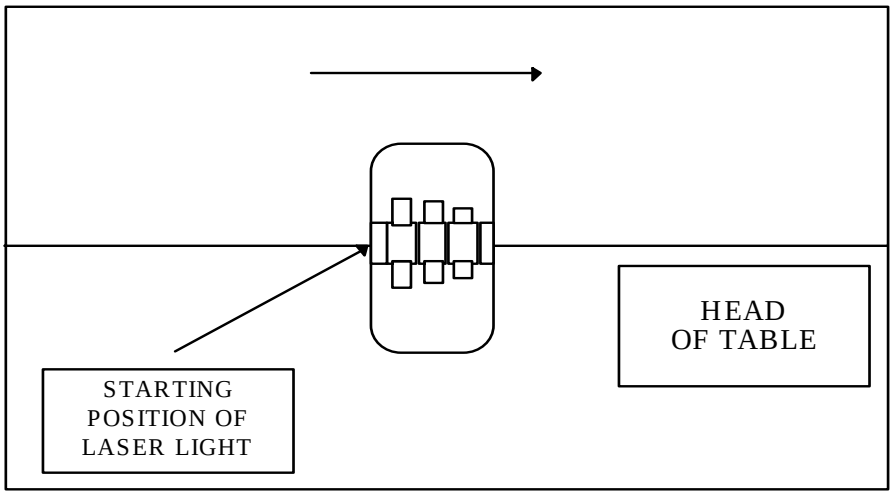
   Pat ID : Enter the phantom serial number.

   Please use zeros (Ø) in the biography and not the letter "O".

   All other fields in the Patient Biography should be left blank.

2. Place the ESP on the mat. Make sure it is straight on the table.
   Use a ruler to align the phantom and move the cross hairs head to foot along the length of phantom to check the alignment.





CORRECT POSITION OF THE ESP IN THE SCAN TABLE

3. Go to the scan menu <F3> and choose "Spine". Then select the default '**Array Spine'** as the scan type. After the arm moves to the back press <Enter>. The arm will move forward to the correct centering point for the scan.

4. Move the arm to center the red laser positioning light over the black line on 'L5' of the ESP. Note that the ESP consists of only 3 complete vertebra (L2, L3, L4).

   Set scan length to 4 inches or approximately 10 cm.

5. Press < **F2** > to Scan.

   Use < **F3** > (rescan) if the Phantom is not centered or does not have all vertebrae visualized.

   Allow the scan to finish on its own; please do not stop it prematurely.

Creating a European Spine Phantom (ESP) Baseline Analysis

1. Select Region of Interest (ROI).

   A) The width of the ROI should be 116 pixels. The ROI height should be 87.

   B) Center the ROI so the Spine Phantom is in the middle.

   C) Ensure that the intervertebral markers lie within the intervertebral spaces.

   Press **<End>**.

2. Mark Inter vertebral Spaces.

   Be sure the lines are centered in the spaces between each vertebrae. They must not intersect any of the vertebral bodies.

   Press **<End>**.

3. Label Vertebrae.

   A) Label the vertebrae L2 - L4.

   Press **<End>**.

   B) At this point, the QDR begins its calculations of the soft tissue and bone thresholds. Wait until the calculations are completed before processing any further.

4. **DO NOT INSERT OR DELETE ANY POINTS**.

   Press **<End>**.

5. Print the Report Screen.

6. Add the scan to your QC database.

7. Archive the baseline scan to an optical or floppy disk.

European Spine Phantom (ESP) Compare

1. Once a baseline European Spine Phantom scan has been established, use that scan as the reference scan within the Compare feature menu for all subsequent scans.

2. After a subsequent scan has been performed, choose Compare at the Analyze menu.

3. Highlight the baseline European Spine Phantom scan and press **<ENTER>**

4. Analysis.

   A) Two images are displayed on the screen. The one on the left is the present scan.

   B) The ROI and bone outline are automatically placed over the scan. Using the arrow keys, move the entire box so it matches as best as possible over the image. When comparing spine scans, move the ROI up and down or left and right as necessary.
   Press **<End>**.

   C) Mark Intervertebral Spaces. If the ROI was matched correctly, no adjustment should be necessary.
   Press **<End>**.

   D) Label Vertebrae (L2 - L4). This is done automatically.
   Press **<End>**.
   At this point, calculations begin. Please do not interrupt them.

   E) **DO NOT INSERT OR DELETE ANY POINTS.**

   Press **<End>**.

   F) The Report Screen is generated.

   G.) Add the scan to your QC database

Whole Body Phantom Protocol

I PHANTOM ASSEMBLY

Before lifting or transporting the phantom, break it down into its individual components. Use care, the impact force of a phantom component dropped from table height can cause severe injury, particularly if the impact is delivered through one of the phantom's beveled edges. Having another person help move the phantom components is strongly recommended.

A thin, gray PVC sheet is attached to the large white plastic piece that contains the two plastic locating pins. This HDPE/PVC combination is the bottom layer (base) of the phantom. Position it on the scanner table such that the PVC is on the bottom (i.e. the gray PVC is in contact with the table pad and the two plastic locating pins project out of the plane of the table towards the ceiling.

Place the second large white plastic piece on top of the phantom base, using the locating pins as a guide. The second piece should be placed such that the beveled edge forms a "V" with the base.

Next, place the medium size white plastic pieces on the phantom, again forming a "V" with the two beveled edges of the middle pieces. Then place the small white plastic pieces on top, forming another "V" with the small pieces. The final assembly will form a pyramid (see Figure 1, side view). This is the only valid configuration for the phantom measurement. All other configurations including adding materials to the phantom, removing pieces of the phantom, scanning the phantom upside down, etc. violate the intended use of the phantom and may produce invalid results.

II PHANTOM POSITIONING

Carefully position the whole body phantom in the center of the scanner table with the head of the phantom at the head of the table. Allow 24" (61cm) of empty air space at the head of the table. Carefully position the phantom parallel with the long axis of the table, using the table pad markings as a guide. When properly centered, there will be a constant 3.5" (8.9 cm) gap between the side of the phantom and the front and back limits of the 4500A scanner table (see Figure 1).

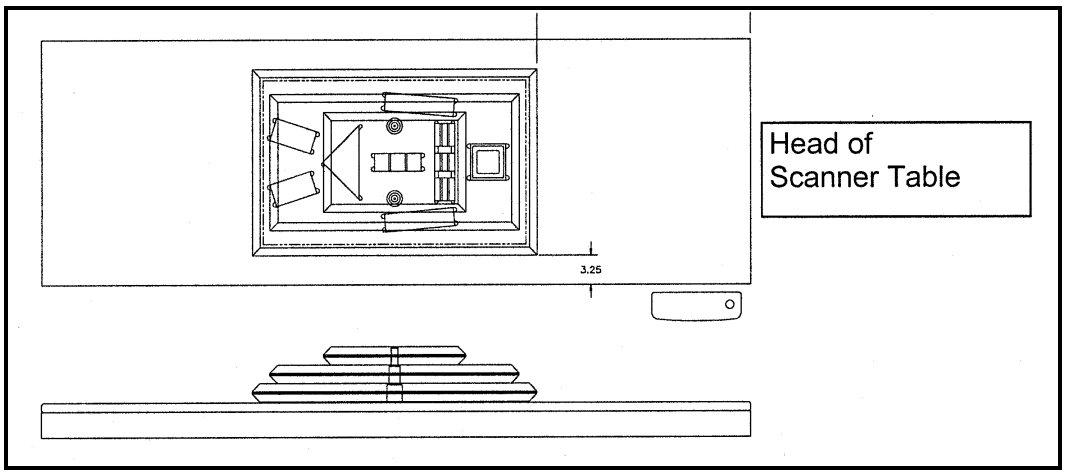


Figure 1. Layout of Whole Body Phantom positioned on the 4500A scanner table. Also shown, the fully assembled phantom viewed from the side. (Note that the amount of empty space between the side of the phantom and the sides of the table will vary depending upon scanner model).

III DATA ACQUISITION - SCANNING THE WHOLE BODY PHANTOM

Make sure that the phantom is centered, is parallel to the long axis of the table and is correctly oriented with respect to the head of the table.

Enter "**WB PHANTOM #xxx**" in the Patient Name field of the Patient Biography (where **xxx** is the serial number of the Whole Body Phantom).

Remove all artifacts from the table surface. Extraneous objects in the scan field will interfere with the measured results in an unpredictable fashion.

Be sure to include the Tissue bar when scanning on the QDR 1500.

Select the standard Adult Whole Body scan mode commonly employed at your facility. Accept the default scan length and scan width. Perform a complete scan of the entire table surface including the phantom. Do not interrupt the scanner during the measurement.

Carefully inspect the scan image to ensure that the phantom was (i) centered, (ii) parallel to the long axis of the scanner table and (iii) the phantom's head appears at the top of the image. If the scan image appears satisfactory, proceed to the analysis section. If not, carefully reposition the phantom according to the instructions in Section II and repeat the scan.

IV ANALYSIS

A. General Comments

The goal of the analysis is to carefully delineate the various body regions in a standard and reproducible fashion, so that measured results will reflect instrument performance, not variations in analysis techniques. Of particular importance are the placement of the head ROI cutline and the cutlines that delineate the ribs, since these two regions affect global body composition and BMD. It is essential that the baseline measurement is technically adequate and that the analysis is performed by direct comparison to the sample analysis on the Hologic diskette labeled: "SAMPLE ANALYSES: WB PHANTOM".

B. Specific Instructions - Hologic QDR systems

Follow the instructions in Sections II and III to acquire a technically adequate scan of the Whole Body phantom. Restore the appropriate scan from the Hologic diskette labeled "SAMPLE ANALYSES: WB PHANTOM" to the analysis workstation. (See Table 1 for the correct scan to restore for your QDR model). Select the newly acquired WB Phantom scan. Then use the Compare feature to register the ROI cutlines of the Sample scan to the newly acquired scan of the WB Phantom. Once the ROI's have been matched as nearly as possible, complete the analysis and print the first and last pages of the report.

Archive the baseline measurement for safekeeping but do not delete it from the analysis workstation. All future whole body phantom measurements will be compared to the initial baseline measurement. After the initial measurement, the sample scan restored from the sample diskette should be deleted.

QDR MODEL #	WB PHANTOM SCAN (RESTORE FROM SAMPLE DISK)
1000W, 1500, 2000 Pencil beam	1000/1500/2000 Pencil WB Phantom
2000 Fan Beam	2000 Fan WB Phantom
4500W	4500W WB Phantom
4500A	4500A WB Phantom

Table 1. Scans to restore for a given QDR model #.

V. INTERPRETATION OF MEASURED VALUES

The phantom measurements should be printed out and placed in a log book. The values for Total BMD and %Fat should be manually plotted on the graph supplied by the HABC DXA Reading Center.